08-25-04

IFW AF/3732

PTO/SB/17 (10/03)
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FEE TRANSMITTAL for FY 2004

Effective 10/01/2003. Patent fees are subject to annual revision.

☒ Applicant claims small entity status. See 37 CFR 1.27.

TOTAL AMOUNT OF PAYMENT ($) 165.00

Complete if Known	
Application Number	09/751,271
Filing Date	December 28, 2000
First Named Inventor	Alferness
Examiner Name	K. Odlund
Art Unit	3732
Attorney Docket No.	29912-702.201

METHOD OF PAYMENT *(check all that apply)*

☐ Check ☐ Credit card ☐ Money Order ☐ Other ☐ None

☒ Deposit Account:

Deposit Account Number: 23-2415

Deposit Account Name: Wilson Sonsini Goodrich & Rosati

The Director is authorized to: *(check all that apply)*

☒ Charge fee(s) indicated below ☐ Credit any overpayments

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FEE CALCULATION

1. BASIC FILING FEE

Large Fee Code	Large Entity Fee ($)	Small Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
1001	770	2001	385	Utility filing fee	
1002	340	2002	170	Design filing fee	
1003	530	2003	265	Plant filing fee	
1004	770	2004	385	Reissue filing fee	
1005	160	2005	80	Provisional filing fee	

SUBTOTAL (1) ($) 0

2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

			Extra Claims		Fee from below		Fee Paid
Total Claims		-20** =		x		=	
Independent Claims		-3** =		x		=	
Multiple Dependent						=	

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description
1202	18	2202	9	Claims in excess of 20
1201	86	2201	43	Independent claims in excess of 3
1203	290	2203	145	Multiple dependent claim, if not paid
1204	86	2204	43	**Reissue independent claims over original patent
1205	18	2205	9	**Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) ($) 0

***or number previously paid, if greater; For Reissues, see below*

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
1051	130	2051	65	Surcharge - late filing fee or oath	
1052	50	2052	25	Surcharge - late provisional filing fee or cover sheet	
1053	130	1053	130	Non-English specification	
1812	2,520	1812	2,520	For filing a request for *ex parte* reexamination	
1804	920*	1804	920*	Requesting publication of SIR prior to Examiner action	
1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner action	
1251	110	2251	55	Extension for reply within first month	
1252	420	2252	210	Extension for reply within second month	
1253	950	2253	475	Extension for reply within third month	
1254	1,480	2254	740	Extension for reply within fourth month	
1255	2,010	2255	1,005	Extension for reply within fifth month	
1401	330	2401	165	Notice of Appeal	
1402	330	2402	165	Filing a brief in support of an appeal	165.00
1403	290	2403	145	Request for oral hearing	
1451	1,510	1451	1,510	Petition to institute a public use proceeding	
1452	110	2452	55	Petition to revive - unavoidable	
1453	1,330	2453	665	Petition to revive - unintentional	
1501	1,330	2501	665	Utility issue fee (or reissue)	
1502	480	2502	240	Design issue fee	
1503	640	2503	320	Plant issue fee	
1460	130	1460	130	Petitions to the Commissioner	
1807	50	1807	50	Processing fee under 37 CFR 1.17(q)	
1806	180	1806	180	Submission of Information Disclosure Stmt	
8021	40	8021	40	Recording each patent assignment per property (times number of properties)	
1809	770	2809	385	Filing a submission after final rejection (37 CFR 1.129(a))	
1810	770	2810	385	For each additional invention to be examined (37 CFR 1.129(b))	
1801	770	2801	385	Request for Continued Examination (RCE)	
1802	900	1802	900	Request for expedited examination of a design application	

Other fee (specify)

* Reduced by Basic Filing Fee Paid

SUBTOTAL (3) $ 165.00

SUBMITTED BY

(Complete *(if applicable)*)

Name *(Print/Type)*	James R. Shay	Registration No. *(Attorney/Agent)*	32,062	*Telephone*	650-493-9300
Signature				Date	August 23, 2004

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TRANSMITTAL FORM

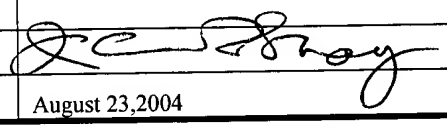
(to be used for all correspondence after initial filing)

Application Number	09/751,271
Filing Date	December 28, 2000
First Named Inventor	Alferness
Art Unit	3732
Examiner Name	K. Odlund
Total Number of Pages in This Submission: 13	Attorney Docket Number: 29912-702.201

ENCLOSURES *(Check all that apply)*

☒ **Fee Transmittal Form**	☐ Drawing(s)	☐ After Allowance communication to Technology Center (TC)
☐ Fee Attached	☐ Licensing-related Papers	☐ Appeal Communication to Board of Appeals and Interferences
☒ **Appellant's Brief (3 copies)**	☐ Petition	☐ Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
☐ After Final	☐ Petition to Convert to a Provisional Application	☐ Proprietary Information
☐ Affidavits/declaration(s)	☐ Power of Attorney, Revocation Change of Correspondence Address	☐ Status Letter
☐ Extension of Time Request	☐ Terminal Disclaimer	☐ Other Enclosure(s) (please identify below):
☐ Express Abandonment Request	☐ Request for Refund	
☐ Information Disclosure Statement	☐ CD, Number of CD(s)	
☐ Certified Copy of Priority Document(s)	Remarks	
☐ Response to Missing Parts/ Incomplete Application		
☐ Response to Missing Parts under 37 CFR 1.52 or 1.53		

SIGNATURE OF APPLICANT, ATTORNEY OR AGENT

Firm or Individual name	James R. Shay, Reg. No. 32,062, WILSON SONSINI GOODRICH & ROSATI
Signature	
Date	August 23,2004

CERTIFICATE OF TRANSMISSION/MAILING

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EV 517 775 162 US

Typed or printed name	Annette Palladino		
Signature	Annette Palladino	Date	August 23, 2004

APPEAL BRIEF
Atty. Docket No. 29912-701.201

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re application of Alferness et al. Appln. No.: 09/751,271 Confirmation No.: 8995 Filed: December 28, 2000 "Mitral Valve Constricting Device, System and Method"	Group Art Unit: 3732 Examiner: K. Odlund

APPELLANTS' BRIEF PURSUANT TO 37 C.F.R. § 1.192

MAIL STOP APPEAL BRIEF - PATENTS
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Appellant submits the following brief in accordance with the provisions of 37 C.F.R. § 1.192 in response to the Final Rejection mailed March 11, 2004. This brief is being filed in triplicate. Unless a check is submitted herewith for the fee required under 37 C.F.R. § 1.192(a) and 1.17(c), please charge said fee to Deposit Account No. 23-2415. Appellant's Notice of Appeal was filed on June 23, 2004. Therefore, this appeal brief is timely filed.

I. REAL PARTY IN INTEREST

The real party in interest is CARDIAC DIMENSIONS, INC. (Assignee) by virtue of an assignment executed by the inventors (Appellants) and recorded by the Assignment Branch of the U.S. Patent and Trademark Office on April 16, 2001 (at Reel 011719, Frame 0019).

II. RELATED APPEALS AND INTERFERENCES

Appellant states that, upon information and belief, Appellants are not aware of any co-pending appeal or interference which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

III. STATUS OF CLAIMS

The application under appeal currently includes claims 25-30 after entry of Appellants' Amendment After Final Rejection.

Claims 25-28 stand rejected as anticipated under 35 U.S.C. § 102(e) by Houser et al. US 2002/0035361 (hereinafter "Houser").[1]

Claims 28-30 stand rejected as being unpatentable under 35 U.S.C. § 103(a) in view of Houser.

Claims 1-24 and 31-50 have been canceled.

The rejections of claims 25-30 are appealed.

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[1] The Examiner's Final Rejection is ambiguous on the point of whether claim 28 stands rejected under § 102 or § 103. While the Examiner included claim 28 in the list of claims rejected under § 102 (Final Rejection at p. 5) and omits claim 28 from the list of claims rejected under § 103 (Final Rejection at p. 12), the Examiner addressed the subject matter of claim 28 with respect to the obviousness discussion under § 103 (Final Rejection at p. 13). Appellants will treat claim 28 as having been rejected under both § 102 and § 103.

IV. STATUS OF AMENDMENTS

Appellants filed an Amendment After Final Rejection on April 22, 2004. The Examiner indicated in an Advisory Action, mailed June 14, 2004, that the proposed amendment presented in the Amendment After Final Rejection would be entered on filing of a Notice of Appeal and an Appeal Brief. The Notice of Appeal was filed June 23, 2004. The claims set forth in the APPENDIX as required by 37 C.F.R. §1.192 (c)(9) therefore correspond to claims as amended by the Amendment After Final Rejection filed April 22, 2004. All amendments have been entered.

V. SUMMARY OF THE INVENTION

Embodiments of the present invention as claimed in the appealed claims are described below with reference to page and line numbers in the instant application, U.S. Patent Application S.N. 09/751,271 entitled "Mitral Valve Constricting Device, System and Method" by Alferness et al. as filed December 28, 2000.

Independent claim 25 recites a method of treating dilated cardiomyopathy of a heart of a patient. The method includes the step of providing a constriction device formed of resilient material having an unstressed C-shape configuration with an effective radius less than a dilated mitral valve annulus and a cross sectional dimension for being received within the coronary sinus of the heart, as illustrated in at least the embodiments of device 30 of Figures 2-5, 7 and 8. The method also includes the step of advancing the constriction device into the coronary sinus of the heart until the constriction device at least partially encircles the mitral valve of the heart, as illustrated in Figures 2-4 and 8. Support for this claim is found, at least, on page 3, line 4, to page 4, line 2; page 5, line 28 to page 7, line 28.

Claim 26 depends from claim 25. In claim 26, the advancing step includes the step of releasably coupling the constriction device to an elongated flexible introducer and moving the constriction device into the coronary sinus with the introducer. Support for this claim is found, at least, on page 3, lines 16-20; page 6, line 27 to page 7, line 21; and Figures 3-6.

Claim 27 depends from claim 26 and adds the steps of releasing the introducer from the constriction device when the constriction device at least partially encircles the mitral valve and removing the introducer from the patient. Support for this claim is found, at least, on page 3, lines 25-27; and page 7, lines 14-18.

Claim 28 depends from claim 26 and adds the step of placing a cylindrical sheath within the coronary sinus of the heart of the patient, with the sheath having a cross sectional dimension for receiving the introducer and constriction device. Also according to claim 28, the advancing step includes the step of guiding the introducer and constriction device into the coronary sinus within the sheath. Support for this claim is found, at least, on page 3, lines 20-24; page 6, lines 18-26; page 7, lines 1-7; and Figures 3-6.

Claim 29 depends from claim 28 and adds the steps of releasing the introducer from the constriction device when the constriction device at least partially encircles the mitral valve and removing the introducer and sheath from the patient. Support for this claim is found, at least, on page 3, lines 25-27; and page 7, lines 14-18.

Claim 30 depends from claim 29 and adds the further step of retracting the sheath until the sheath is proximal to the constriction device prior to releasing the introducer from the constriction device. Support for this claim is found, at least, on page 7, lines 8-11; and Figure 4.

VI. ISSUES

Appellants respectfully request the Board of Patent Appeals and Interferences to review the following issues on appeal:

1. Whether claim 25 is anticipated by Houser under 35 U.S.C. § 102(e).
2. Whether claim 26 is anticipated by Houser under 35 U.S.C. § 102(e).
3. Whether claim 27 is anticipated by Houser under 35 U.S.C. § 102(e).
4. Whether claim 28 is anticipated by Houser under 35 U.S.C. § 102(e) or would have been obvious to a skilled artisan in view of Houser under 35 U.S.C. § 103(a).

5. Whether claim 29 would have been obvious to a skilled artisan in view of Houser under 35 U.S.C. § 103(a).
6. Whether claim 30 would have been obvious to a skilled artisan in view of Houser under 35 U.S.C. § 103(a).

VII. GROUPING OF CLAIMS

Appellants do not intend for claims 25-30 to stand or fall together. Rather, Appellants will prove the patentability of claim 25 (Group I), claims 26 and 28 (Group II), claims 27 and 29 (Group III) and claim 30 (Group IV). Each of the above named groups of claims will stand or fall separately from one another. The reasons these four groups of claims should stand or fall separately are set forth in the Argument section below.

VIII. ARGUMENT

Appellants respectfully submit that claims 25-30 are in proper form and are patentable over the prior art of record. More specifically, Appellants contend that Houser does not anticipate claims 25-28 under 35 U.S.C. § 102(e) and does not render claims 28-30 obvious under 35 U.S.C. § 103(a).

Citations below are made to page, column, line or paragraph numbers of Houser et al. US 2002/0035361.

The legal standard for anticipation

The Examiner's rejection of claims 25-28 in this case is based on anticipation. A rejection for anticipation under section 102 requires that each and every limitation of the claimed invention be disclosed in a single prior art reference with sufficient precision and detail to establish that the subject matter existed in the prior art. In re Paulson, 30 F.3d 1475, 1478-79, 31 USPQ2d 1671, 1673 (Fed. Cir. 1994); Verve, LLC v. Crane Cams, Inc., 311 F.3d 1116, 1120, 65 USPQ2d 1051 (Fed. Cir. 2002). The reference must describe the applicant's claimed invention

sufficiently to have placed a person of ordinary skill in the field of the invention in possession of it. In re Spada, 911 F.2d 705, 708, 15 USPQ2d 1655, 1657 (Fed. Cir. 1990).

The legal standard for obviousness

During patent examination the PTO bears the initial burden of presenting a prima facie case of unpatentability. In re Oetiker, 977 F.2d 1443,1445, 24 USPQ2d 1443, 1444 (Fed.Cir. 1992). To establish a prima facie case of obviousness, it is necessary for the examiner to present evidence, preferably in the form of some teaching, suggestion, incentive or inference in the applied prior art, or in the form of generally available knowledge, that one having ordinary skill in the art would have been led to combine the relevant teachings of the applied references in the proposed manner to arrive at the claimed invention. Ex parte Levengood, 28 USPQ2d 1300, 1301 (Bd. Pat. App. & Int. 1993). Failure to meet that burden requires overturning the obviousness rejection. In re Rijckaert, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed.Cir. 1993).

A prima facie case of obviousness can be rebutted if the applicant can show that the art teaches away from the claimed invention. In re Geisler, 116 F.3d 1465, 1469, 43 USPQ2d 1362, 1365 (Fed. Cir. 1997); In re Sponnoble, 405 F.2d 578, 587, 160 USPQ 237, 244 (CCPA 1969). In particular, the use of hindsight by the Examiner is improper when setting forth an obviousness rejection. An inventor's explanation of how the invention works does not render obvious that which is otherwise unobvious. In re Glaug, 283 F.3d 1335, 1341-42, 62 USPQ2d 1065 (Fed. Cir. 2002).

The Houser Reference

Houser describes a variety of "mechanical valve resizing systems and methods . . . entail[ing] the positioning, deployment, and securing of one or more clips to bring the annular edges of a valve . . . together to correct for valvular regurgitation." (Houser ¶ 115) While Houser shows many different clip embodiments, Houser discloses only one that may be

delivered to the mitral valve annulus via the coronary sinus. (Houser ¶¶ 138-139 and Fig. 42) This embodiment served as the basis of the Examiner's rejections.

As shown in Houser Fig. 42, clips 498 are substantially straight (i.e., have an infinite effective radius) with curved anchor sections at their ends. After deployment, the clip ends engage opposing sides of the valve annulus, and the straight clip body extends across the valve itself to draw the edges of the valve together. Because the clips are designed to extend across the valve and not around the valve, Houser never describes the relative radii of the clips with respect to the valve annulus.

Clips 498 are delivered through the coronary sinus to the valve annulus via a catheter 490 together with a plunger and stylet. (Houser ¶ 139) A number of delivery ports 492 corresponding to the number of clips 498 to be delivered are formed in catheter 490. Once the delivery ports 492 are aligned with the valve annulus, each clip is urged out of its delivery port by the plunger and stylet and is pushed through the coronary sinus wall and the adjacent heart tissue so that the anchoring members on the ends of the straight clip engage the valve annulus, as shown in Fig. 42. Houser does not describe any releasable coupling or uncoupling between the delivery mechanism and the clip, nor does Houser describe any relative movement between the catheter and the device during delivery or deployment.

Group I: Claim 25 is patentable over Houser

Method claim 25 recites the provision of "a constriction device formed of resilient material having an unstressed C-shape configuration with an effective radius less than a dilated mitral valve annulus" and the advancement of that device into the coronary sinus "until the constriction device at least partially encircles the mitral valve of the heart." The Examiner points to Houser ¶ 14, ¶¶ 121-143, claims 1-97 and Figs. 27A-37B to support her contention that Houser anticipates claim 25. (Final Rejection at pp. 8-9) Houser, however, fails to disclose a device with the recited unstressed effective radius and does not show the advancement of any

device to partially encircle the mitral valve. Because Houser does not does each and every limitation of claim 25, Houser cannot anticipate claim 25 under § 102.

For at least these reasons, the rejection of claim 25 (and claims 26-30, which depend from claim 25) is improper and should be overturned.

Group II: Claims 26 and 28 are patentable over Houser

Claims 26 and 28 depend from claim 25 and are therefore patentable over Houser for the reasons discussed above with respect to claim 25.

In addition, the advancing step of claim 26 includes the steps of "releasably coupling the constriction device to an elongated flexible introducer and moving the device into the coronary sinus with the introducer." The Examiner once again points to Houser ¶ 14, ¶¶ 121-143, claims 1-97 and Figs. 27A-37B—in particular, element 436 of Fig. 37—to support her assertion that Houser anticipates claim 26. (Final Rejection at p. 9)

Claim 28 further limits claim 26 by reciting the step of placing a cylindrical sheath within the coronary sinus. The Examiner points out that Houser fails to disclose this limitation (Final Rejection at p. 13) but suggests that modification of Houser to include this step would have been obvious. (Final Rejection at p. 15)

Houser's discussion of his coronary sinus delivery system refers back to the plunger and stylet "as described above" (Houser ¶ 139), presumably the delivery system shown in Houser Figs. 37-38. In Houser Figs. 37-38, a plunger 448 at the distal end of a stylet 450 simply pushes the clip out the end of the catheter. There is no releasable coupling between the plunger and the clip, such as described in Appellants' specification. Houser does not disclose the step of releasably coupling a device to an introducer and therefore cannot anticipate claim 26 under § 102.

For at least these reasons, the rejection of claim 26 (and claims 27-30, which depend from claim 26) is improper and should be overturned.

Group III: Claims 27 and 29 are patentable over Houser

Claim 27 depends from claim 26, and claim 29 depends from claim 28 which depends from claim 26. Claims 27 and 29 are therefore patentable over Houser for the reasons discussed above with respect to claim 26.

In addition, claim 27 includes the steps of releasing the introducer from the constriction device when the constricting device at least partially encircles the mitral valve and removing the introducer from the patient. In her rejection of claim 27 under § 102, the Examiner asserts that Houser discloses these steps, pointing to Houser ¶ 14, ¶¶ 121-143, claims 1-97 and Figs. 27A-37B. (Final Rejection at p. 9) As stated above, however, Houser's plunger and stylet are never coupled to Houser's device. Houser therefore does not disclose a releasing step as recited in claim 27 and cannot anticipate claim 27 under § 102.

Likewise, claim 29 further limits claim 28 to include the steps of releasing the introducer from the constriction device when the constricting device at least partially encircles the mitral valve and removing the introducer and sheath from the patient. The Examiner acknowledges that Houser fails to disclose these method steps. (Final Rejection at p. 13) Nonetheless the Examiner asserts—without pointing to anything in the prior art to support her assertion—that the addition of these method steps would have been obvious. (Final Rejection at p. 15)

Once again, as stated above, Houser's plunger and stylet are never coupled to Houser's device. Houser therefore does not disclose a releasing step as recited in claim 29. The Examiner has failed to make a prima facie case for unpatentability of claim 29. Rather, the Examiner's basis for the rejection of claim 29 is based solely on hindsight and is therefore improper. Houser does not render claim 29 unpatentable for obviousness under § 103(a).

For at least these reasons, the rejection of claims 27 and 29 (and claim 30, which depends from claim 29) are improper and should be overturned.

Group IV: Claim 30 is patentable over Houser

Claim 30 depends from claim 29 and is therefore patentable over Houser for the reasons discussed above with respect to claim 29.

In addition, claim 30 recites the step of retracting the sheath until the sheath is proximal to the constriction device prior to releasing the introducer from the constriction device. Once again, the Examiner acknowledges that Houser fails to disclose this method step (Final Rejection at p. 13) but nonetheless asserts—without pointing to anything in the prior art to support her assertion—that the addition of this method step would have been obvious. (Final Rejection at p. 15) In fact, Houser never discloses or suggests any kind of releasable connection between an introducer and a mitral valve device, much less a release mechanism requiring withdrawal of a sheath from the device. The Examiner has failed to make a prima facie case for unpatentability of claim 30. Rather, the Examiner's basis for the rejection of claim 30 is based solely on hindsight and is therefore improper. Houser does not render claim 30 unpatentable for obviousness under § 103(a).

For at least these reasons, the rejection of claim 30 is improper and should be overturned.

CONCLUSION

For the reasons stated above, claims 25-30 are patentable over the prior art of record, and the rejections those claims under 35 U.S.C. § 102(e) and § 103(a) are improper and should be withdrawn. Appellants respectfully ask the Board to overturn the Examiner's rejection with instructions to allow the claims.

The USPTO is directed and authorized to charge all required fees to Deposit Account No. 23-2415.

Respectfully submitted,

Date: 8/23/04

James R. Shay, Reg. No. 32062

APPENDIX

Claims on Appeal

25. (Original) A method of treating dilated cardiomyopathy of a heart of a patient, the method including the steps of:

providing a constriction device formed of resilient material having an unstressed C-shape configuration with an effective radius less than a dilated mitral valve annulus and a cross sectional dimension for being received within the coronary sinus of the heart; and

advancing the constriction device into the coronary sinus of the heart until the constriction device at least partially encircles the mitral valve of the heart.

26. (Original) The method of claim 25 wherein the advancing step includes releasably coupling the constriction device to an elongated flexible introducer and moving the constriction device into the coronary sinus with the introducer.

27. (Original) The method of claim 26 including the further steps of releasing the introducer from the constriction device when the constriction device at least partially encircles the mitral valve and removing the introducer from the patient.

28. (Original) The method of claim 26 including the further step of placing a cylindrical sheath within the coronary sinus of the heart of the patient, the sheath having a cross sectional dimension for receiving the introducer and constriction device, and wherein the advancing step includes the step of guiding the introducer and constriction device into the coronary sinus within the sheath.

29. (Original) The method of claim 28 including the further steps of releasing the introducer from the constriction device when the constriction device at least partially encircles the mitral valve and removing the introducer and sheath from the patient.

30. (Original) The method of claim 29 including the further step of retracting the sheath until the sheath is proximal to the constriction device prior to releasing the introducer from the constriction device.